DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2014

OrthoHub, Incorporated
Ms. Peggy McLaughlin
Regulatory Consultant
999 Menlo Oaks Drive
Menlo Park, California 94025

Re: K140550
Trade/Device Name: OrthoHub External Fixator Software
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: OSN
Dated: July 30, 2014
Received: August 1, 201

Dear Ms. McLaughlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140550

Device Name
OrthoHub External Fixator Software

Indications for Use *(Describe)*
The OrthoHub External Fixator Software is used with Smith & Nephew Taylor Spatial Frame (TSF) rings and struts for the treatment of traumatic or reconstructive tibia deformities. It is used to generate a prescription of strut adjustments to provide to the patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5.0 510(k) Summary

Submitters Name and Address
OrthoHub, Inc.
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Contact Person
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Date Prepared
30 July 2014

Medical Device

Proprietary Name:	OrthoHub External Fixator Software
Common Name:	Orthopedic Software for Treatment
Classification Name:	Software for single/multiple component metallic bone fixation appliances and accessories
Classification Number:	21 CFR Sec. 888.3030
Class:	II
Product Code:	OSN

Predicate Devices

Smith & Nephew, Inc. Spatialframe V4.1 Web-based Software (K110069)
Smith & Nephew, Inc. Circular Fixation System (K093047)
Smith & Nephew, Inc. Taylor Spatial Frame (K970748)

These devices have not been subject to a design-related recall.

No reference devices were used in this submission.

Indications For Use

The OrthoHub External Fixator Software is used with Smith & Nephew Taylor Spatial Frame (TSF) rings and struts for the treatment of traumatic or reconstructive tibia deformities. It is used to generate a prescription of strut adjustments to provide to the patient.

Device Description

The OrthoHub External Fixator Software is a software program used on a Macintosh Computer. The software is used to generate a prescription which details adjustments required for the treatment of traumatic or reconstructive tibia deformities when using the Smith and Nephew Taylor Spatial Frame External Fixator hardware. Users input orthogonal x-ray images of a patient's deformity taken after installation of the fixator hardware on the patient. The software creates a colored graphical representation of the bones and orthopedic fixator hardware shown in the x-rays, and the user adjusts this graphical representation so that it best matches the underlying x-rays. The user then defines a correction rate, and the software generates a prescription of strut adjustments to correct the deformity. This prescription is provided to the patient for strut adjustment during the prescription period.

Intended Use

The OrthoHub External Fixator Software is used to assist the clinician in adjusting the Smith & Nephew Taylor Spatial Frame (TSF) External Fixator by creating a patient adjustment schedule. The OrthoHub software receives x-ray images of the deformity and installed fixator hardware and produces a prescription recommending adjustments to the fixator that define a correction path for the deformity. The software is used as an accessory to the commercially available hardware as detailed in the Instructions for Use, specifically, Smith and Nephew's Taylor Spatial Frame rings and struts.

The intended use of the OrthoHub External Fixator Software is identical to the software component of the predicate devices.

Comparison of the technological characteristics with the predicate device

Both the OrthoHub Software and the predicates are software which, with the input of patient specific measurements or x-ray images, provides recommended adjustments to the external hardware to treat a patient's deformity. The software performs mathematical calculations to provide a prescription for strut adjustment after the Smith & Nephew hardware has been placed on the patient and while the patient is wearing the external hardware to correct a deformity of the tibia.

The following technological differences exist between the subject and predicate devices:

- Use of a Macintosh computer (versus predicate's web-based software run in the cloud)
- Use of x-ray images of patient (versus practitioner's input of measurements from the x-ray images)

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Software Verification & Validation Testing

Mechanical Bench Top Side by Side Comparison Testing

Results of the testing confirmed that the software performs as intended. The software produced recommended adjustments as appropriate for the inputs (patient x-rays) and user entered information (fixator hardware, time for prescription/treatment). Results of performance testing through the bench testing and software verification and validation process demonstrate that the OrthoHub External Fixator Software functions as intended and is substantially equivalent to the predicate devices.

Conclusions

The OrthoHub External Fixator Software has the same intended use and indications and utilizes the same technology as the predicates. Performance testing and software verification and validation demonstrate that the OrthoHub External Fixator Software functions as intended. Thus, the OrthoHub External Fixator Software has been shown to be substantially equivalent to the predicate devices.